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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FRAZIER, BARBARA S

ART UNIT

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1611

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,831	Applicant(s) TOGUCHIDA, JUNYA	
	Examiner BARBARA FRAZIER	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 20-36 is/are pending in the application.
- 4a) Of the above claim(s) 29-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 20-28, 35 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/25/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 11 and 20-36 are pending in this application. Addition of new claims 35 and 36 is acknowledged. Claims 1-10 and 12-19 stand canceled.
2. Claims 29-34 are withdrawn from consideration.
3. Claims 11, 20-28, 35, and 36 are examined.

Election/Restrictions

4. Applicant's election without traverse of Group I, claims 11 and 20-31, and the species (5Z, 9 β , 11 α , 13E)-17,17-propano-11,16-dihydroxy-9-chloroprostanoic acid in the reply filed on 3/27/08 is acknowledged.
5. Applicants did not present any arguments against the basis for the restriction requirement in the Office action mailed 7/9/08; accordingly, Applicant's election without traverse has been maintained.
6. The requirement is still deemed proper and is therefore made FINAL.
7. Claims 29-34 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/27/08.
8. Claims 35 and 36 will be examined with the elected invention.
9. Claims 11, 20-28, 35, and 36 are examined.

Information Disclosure Statement

10. Applicant's statement in the reply filed 12/9/08 that foreign patents previously not considered have had corresponding documents written in English submitted is duly noted; accordingly, said foreign patents previously not considered have now been marked as considered, to the extent that each patent was submitted with a corresponding document written in English. An updated signed copy of Applicant's form 1449 filed 1/25/06 is attached.

Specification

11. Applicant's amendment filed 12/9/08 which incorporates by reference the following patents is duly noted: EP 860430; WO 99/33794; EP 974580; WO 2003/74483; WO 95/19964; WO 98/28264; WO 99/19300; EP 0911321; US 4,132,738; US 3,965,143; WO 98/34916; JP-A-8-239356; US 4,692,464; JP-A-61-249951; US 4,863,961; and US 3,985,791.

Claim Rejections - 35 USC § 112

12. The rejection of claims 11, 21, 22, and 26 under 35 U.S.C. 112 is withdrawn in view of Applicant's amendments to claims 11, 21, 22, and 26 deleting the phrase "and/or".

13. The rejection of claims 27 and 28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in view of Applicant's amendment to claim 27.

14. The rejection of claims 27 and 28 under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling, is withdrawn in view of Applicant's amendment to claim 27.

15. The rejection of claims 11 and 21-28 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's amendment to claim 11.

Claim Rejections - 35 USC § 103

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. As Applicants correctly point out, in the previous rejection of claims 11 and 21-28 under 35 U.S.C. 103(a), the omission of claim 20 was a typographical error, and was intended to be included with this rejection.

18. Claims 11, 20-28, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paralkar (EP 1205189) in view of Tani et al (Bioorganic and Medicinal Chemistry, Vol. 10, pp. 1107-1114, 2002) and Fortier et al (J. Bone Joint Surg., Vol. 84-B, pp. 276-288, 2002).

The claimed invention is drawn to a method for treating cartilage-related disease, which comprise administering a composition consisting essentially of a substance having an EP2 agonist activity to a subject in need of stimulating chondrocyte growth (see claim 11). Applicants have elected the species (5Z, 9 β , 11 α , 13E)-17,17-propano-11,16-dihydroxy-9-chloroprostano-5,13,19-trienoic acid (see claims 27, 28, 35, and 36) as the substance having an EP2 agonist activity.

Paralkar teaches a method of promoting bone growth comprising a prostaglandin agonist which is an EP2 selective agonist (reference claims 9 and 11). Paralkar also teaches that representative uses of the therapy comprising an EP2 selective agonist is to limit or treat cartilage defects or disorders (page 4, paragraph 38). Since a subject in need of limiting or treatment of cartilage defects or disorders would also be in need of stimulating chondrocyte growth, the invention of Paralkar would be given to the same population as that identified in the claimed invention.

Paralkar does not teach the method utilizing the EP2 agonist species (5Z, 9 β , 11 α , 13E)-17,17-propano-11,16-dihydroxy-9-chloroprostano-5,13,19-trienoic acid.

Tani et al teach that (5Z, 9 β , 11 α , 13E)-17,17-propano-11,16-dihydroxy-9-chloroprostano-5,13,19-trienoic acid is a potent and selective EP2-receptor agonist (compound 4c, pages 1108 and 1110).

Fortier et al teach insulin-growth factor-I enhances cell-based repair of articular damage (title).

It would have been obvious to one of ordinary skill in the art at the time of the invention that, since Paralkar teaches a method of treating cartilage defects or disorders comprising a prostaglandin agonist which is an EP2 selective agonist, and Tani et al teach (5Z, 9 β , 11 α , 13E)-17,17-propano-11,16-dihydroxy-9-chloroprostano-5,13,19-trienoic acid is a potent and selective EP2-receptor agonist, administration of (5Z, 9 β , 11 α , 13E)-17,17-propano-11,16-dihydroxy-9-chloroprostano-5,13,19-trienoic acid would be effective at treating cartilage defects or disorders, thus rendering instant claims 11, 27, 28, 35, and 36 obvious.

Regarding claim 20, Paralkar teach that the EP2 selective agonist may be used to treat cartilage disorders (page 4, paragraph 38).

Regarding claim 21, it would have been obvious to one of ordinary skill in the art at the time of the invention that treating cartilage defects or disorders as taught in Paralkar would include inhibiting cartilage calcification, inhibiting cartilage degradation or to stimulate new cartilage, thus rendering instant claim 21 obvious.

Regarding claims 22-25, it would have been obvious to one of ordinary skill in the art at the time of the invention, that if the EP2 selective agonist inhibits cartilage calcification, then the EP2 selective agonist would inhibit osteopontin protein expression, which is responsible for pathological mineralization in articular cartilage. Additionally, it would have been obvious to one of ordinary skill in the art at the time of the invention, that if the EP2 selective agonist promotes cartilage growth, then the EP2 selective agonist would stimulate cyclin D1 protein expression, since cyclin D1 stimulation contributes to increase chondrocyte growth, thus rendering obvious instant claims 22-25.

Regarding claim 26, it would have been obvious to one of ordinary skill in the art at the time of the invention that since Paralkar in view of Tani et al. teach a method of treating cartilage defects or disorders comprising a prostaglandin agonist which is an EP2 selective agonist (see supra) and Fortier et al. teach insulin-growth factor-I enhances cell-based repair of articular damage, that a method utilizing a pharmaceutical composition combining the two would similarly be useful in treating cartilage defects or disorders and would render claim 26 obvious. "It is prima facie

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obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.)

Response to Arguments

19. Applicant's arguments filed 12/9/08 have been fully considered but they are not persuasive.

Applicants argue that the currently presented claim 1 and its dependent claims clearly set forth the subject as consisting essentially of a substance having an EP2 agonist activity. Applicants argue that Paralkar is directed to a combination of prostaglandin agonist (including selective EP2 agonists) and a HMG-CoA reductase inhibitor, in which both compounds are essential active ingredients, and does not teach that the prostaglandin compound by itself is effective for treating cartilage-related disease, or that the EP2 agonist promotes the formation of cartilage by itself.

This argument is not persuasive because Applicants are basing their argument on the use of the more restrictive bridging term "consisting essentially of", which is intended to limit the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristics of the claimed invention" (see

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MPEP 2111.03). However, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase consisting essentially of’ for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”). The instant specification does not clearly indicate that the HMG-CoA reductase inhibitor compounds of Paralkar would materially affect the basic and novel characteristics of the claimed invention; on the contrary, the specification teaches that the remedy of the present invention may be administered as a combined preparation, and especially may be used with medicaments for treating other bone diseases (see page 63, lines 4-10 of the specification). It is further noted that the combined medicaments listed on page 63 of Applicant’s specification are listed as examples, and the specification does not limit the combined medicaments to said examples. Therefore, compounds known for treating cartilage-related diseases, including the HMG-CoA reductase inhibitors taught by Paralkar, do not materially affect the basic and novel characteristics of the claimed invention, and reasonably read on the claimed invention.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
March 27, 2009

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